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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|--|----------------------|-------------------------|------------------|
| 09/935,344 | 08/23/2001 | Vic Jira | 115091.00101 | 8106 |
| 27557 | 7590 07/02/2003 | | | |
| BLANK ROME COMISKY & MCCAULEY, LLP | | | EXAMINER | |
| | TREET, N.W., SUITE 10 TON, DC 20006 | LUCAS, ZACHARIAH | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | ~ |
| | ON, DC 20006 | • | DATE MAILED: 07/02/2003 | 5 |
| WASHING | | | ART UNIT | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|--|---|--|--|--|--|
| • | 09/935,344 | JIRA ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Zachariah Lucas | 1648 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 36(a). In no event, however, may a reply be to within the statutory minimum of thirty (30) day ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDON | imely filed ays will be considered timely. m the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| 1) Responsive to communication(s) filed on 23 A | <u> August 2001</u> . | | | | | |
| 2a)☐ This action is FINAL . 2b)☐ Th | is action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | |
| 4) Claim(s) 1-12 is/are pending in the application | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)☐ Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 1-12 are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informa | ary (PTO-413) Paper No(s) I Patent Application (PTO-152) | | | | |

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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to antiviral vaccines comprising one or more heat-inactivated viral antigens, classified in class 424, subclass 204.1.
 - II. Claims 10-12, drawn to therapeutic compositions comprising a denatured pathogen antigen, and a denatured tissue from a pathogen infected host, classified in class 424, subclass 184.1.

For each of Groups I and II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I or II, and to one of inventions identified below.

The Applicant is required to elect one of the viral pathogens listed in claims 2 or 4.

The inventions are distinct, each from the other because of the following reasons:

2. The various inventions listed in claims 2 and 4 are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the subcombinations has separate utility. Each of them is independently usable as a composition for

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the treatment of, or for inducing an immune reaction against, infection by a different viral pathogen.

3. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not rely on the particulars of the subcombination for patentability, but relies on the combination of the subcombination with another composition. The subcombination has the same separate utility as does the composition, the ability to act as a vaccine or therapeutic against pathogenic infections.

Conclusion

- 4. Because these inventions are distinct for the reasons given above, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.
- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z Lucas

Patent Examiner June 26, 2003

JAMES HOUSEL

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600